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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,734	12/21/2005	Mark L. Witten	12241-008-999	8590
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NEW YORK, NY 10017			PAPER NUMBER	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/539,734

**Applicant(s)**

WITTEN, MARK L

**Examiner**

MAURY AUDET

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 6/20/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☒ Claim(s) 1-15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/CDC)
- Paper No(s)/Mail Date 6/20/05

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Originally filed claims 1-15 are under examination. It is noted that the same claims were examined in full by this Examiner in Applicant's related PCT/US 03/040259.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, 11, and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (US 5,830,177).

Li et al. teach that “[a]gents useful in conditions of hair loss (alopecia) are those which stimulate hair growth, or those which inhibit the hair loss. Hair growth stimulators are generally well known, and include, but are not limited to, minoxidil, substance-P, [8 other specific agents], and “the like known hair growth stimulators” (col. 4, lines 32-38). Li et al. teach any known means administering such “hair loss” products as substance P (col. 5, lines 16-23), e.g. via aerosol administration (col. 7, lines 1-12; Applicant’s claim 7), which intrinsically includes “topically” (Applicant’s claim 11), and “transdermally” (Applicant’s claim 13; which is any medication administered in a form for absorption through the skin, which aerosol falls within since sprayed on; it is noted that Li et al. acknowledge the transdermal administration of such compounds as well at col. 1, lines 43-49).

As concerns Applicant's claims 2-4, drawn to specific populations who lose hair; Li et al. is deemed to anticipate treating any population subspecies which incurs hair loss, including these populations (just as the genus of Applicant's claim 1 is drawn to).

As concerns claim 5 and 15 and any "bioactive analogue" or "substance P analog" (notwithstanding the arguable antecedent basis issues surrounding both phrases, see below) that has the native substance P backbone, this is deemed to equally encompass "substance P" for which Li et al. is drawn to since no clear guidance is claimed as to what falls within the meaning of "analog". Namely, an analog, as broadly defined in the art, contemplates a single elemental change, which could include a simple shift in stereochemistry at a single point, wherein the native chemical structure of substance P has not been changed, but rather only altered positioning. There is no clear definition for either phrase found in the description to determine whether native substance P, with stereochemical modification but no structural alteration, would not meet the limitations of these "analog/analogue" claims and thus still be anticipated by Li et al., as constituting substance P (or "the like").

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-6, 8-10, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. ((US 5,830,177) in view of Witten et al. (US 5,945,508).

Li et al. is discussed above. Li et al., although teaching the use of substance P of the same purpose including compounds having “the like” effect, and that it may be administered by aerosol; does not expressly teach use of the known bioactive analogue (analog) of [Sar9, Met(O2)11]-substance P (claim 6) or micrometer ranges for administering substance P or any analog thereof by aerosol administration (claims 8-10).

Witten et al. teach use of the specific analog [Sar9, Met(O2)11]-substance P (col. 4, lines 36-27), as well as all other analogs presently claimed (col. 4, lines 30-50), well as the aerosol administration route of administering this analog (col. 5, lines 3-4), including in an amount of 1  $\mu$ m (micrometer) (col. 12, line 31). Witten et al., at col. 4, line 30, also evidences that the RPKPQQFFGLM-NH<sub>2</sub> amino acid backbone is in fact the native substance P structure.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use any substance P analog (or bioactive analog/analogue), including the [Sar9, Met(O2)11]-substance P analog, for the same purpose of treating hair loss as known for native substance P, in Li et al., because Witten et al. advantageously teach that this and other known analogs of substance P work either equivalently or more effectively. Furthermore, Li et al.'s teaching that other like compounds are contemplated, e.g. “the like known hair growth stimulators” of substance

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P for the same purpose, provides clear motivation to use other known compounds such as the substance P analogs of Witten et al., capable of carrying out the same or more optimally results, any of which are equally predictable in function: treating hair loss.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use any routine amount or range, including anywhere within 0.001 to 50  $\mu\text{m}$  (or 0.05 to 10 or 0.1 to 5), in Li et al., because Witten et al. advantageously teach that 1  $\mu\text{m}$ , falling within any of these ranges is a therapeutic amount for the use of substance P in at least one of its other known uses, and the routine optimization of this amount depending on all the variable parameters specific to the patient in question, would have been merely a matter of routine optimization, depending on the desired results for this known compound/analog thereof, for their known use.

Claims 6 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. ((US 5,830,177) in view of Pallenberg et al. (US 5,539,845).

Li et al. is discussed above. Li et al., although teaching aerosol (topical/transdermal) delivery of substance P, does not expressly teach subcutaneous administration, e.g. just below the skin of substance P.

Pallenberg et al. is cited merely by example to show the well known administration of peptides via subcutaneous route for hair loss (e.g. col. 2, lines 5-21).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer substance P via the topical route or subcutaneous route in Li et al., because even though the topical route is preferred since less invasive and acts transdermally to go to the hair root, the subcutaneous route also

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goes directly to the hair root, and in this sense equally works or would be advisable as a route of administration, as the advantageous teachings of Pallenberg et al. are directed.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Claim Objections***

Claims 1-15 are objected to because of the following informalities:

### ***Sequence Rules***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. 37 CFR 1.821(a) presents a definition for “nucleotide and/or amino acid sequences.” *SPECIFICALLY, the instant application contains an unbranched specifically defined sequence of more than four amino acids, namely at e.g. claims 1 and 15, and specification page 3 and 6, the peptide RPKPQQFFGLM-NH<sub>2</sub> is recited without an appropriate sequence identifier (e.g. SEQ ID NO: 1), as well as all analogs thereof, wherein an XAA annotation should be defined to each such SEQ ID NO:.* Nucleotide and/or amino acid sequences as used in 37 CFR 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. Branched sequences are specifically excluded from this definition. Sequences with fewer than four specifically defined nucleotides or amino acids are specifically excluded from this section. “Specifically defined” means those amino acids other than “Xaa” and those nucleotide bases other than “n” defined in accordance with the World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (1998), including Tables 1 through 6 in Appendix 2 (see MPEP § 2422).

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Since the present sequence compliance request is being sent along with the Office Action on the merits (in the interests of compact prosecution, and since no sequences are expressly claimed), Applicant is given **THREE MONTHS** (instead of the normal **ONE MONTH**, or **THIRTY DAYS**, whichever is longer), from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Appropriate correction is required.

#### ***Claim Observation***

In claim 3, the term "loss" should be spelled "lost".

In claims 5-6 versus claim 1, is the invention drawn to a "bioactive analog" or "analogue". The latter in claims 5-6 arguably has no antecedent basis, even if the meaning can be extrapolated. Appropriate amendment for consistency is required.

In claim 7 and 15, the phrase "substance P analog or bioactive analog" borders on a 112<sup>nd</sup> antecedent basis issue, but is presently given the broadest reasonably interpretation of the claims. In claim 1, technically only bioactive analog has antecedent basis. As claim 1 is to "substance P OR a bioactive analog", not a substance P analog or a bioactive analog. In reality claim 7 is really simply redundant, and it is assumed, Applicant meant the language of claim 1, e.g. either substance P itself or a bioactive analog thereof. Appropriate correction is required for consistency.

In claims 14 and 15, the term "Substance P" has been capitalized, whereas in all other recitations it is in lower case. For consistency Applicant is requested to adopt one approach or the other.

#### ***Trademark Observation***



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It is noted the specification (e.g. page 3 bottom onward) has identified the Trademark Homspera followed by "TM" throughout the specification. This is deemed acceptable according to MPEP 609.01(v), under "Examiner's Note" wherein it is noted that EITHER capitalization or the words followed by "TM" are acceptable and proper identifiers for Trademarks:

"Capitalize each letter of the word in the bracket OR include a proper trademark symbol, such as <sup>TM</sup> or © following the word."

Here, in all places, Applicant has carried out the latter. Thus, capitalization is not also required.

It is also noted that the first recitation of this Mark, identified its structure as [Sar(Met(O2)11)-Substance P.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA, 3/15/08

/Maury Audet/  
Examiner, Art Unit 1654